UNITED STATES DISTRICT COURT FOR THE

NORTHERN DISTRICT OF OKLAHOMA

IN RE: GENENTECH HERCEPTIN (TRASTUZUMAB) MARKETING AND SALES PRACTICES LITIGATION.) Case No. 16-MD-2700-TCK-TLW

REDACTED TRANSCRIPT OF RECORDED PROCEEDINGS
AUGUST 12, 2016
BEFORE THE HONORABLE T. LANE WILSON, MAGISTRATE JUDGE PRESIDING

DISCOVERY CONFERENCE

Greg Bloxom, RMR, CRR
United States Court Reporter
Northern District of Oklahoma

A P P E A R A N C E S
(TELEPHONIC)

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PROCEEDINGS:

THE DEPUTY COURT CLERK: This is 16-MD-2700-TCK-TLW, In Re: Genentech Herceptin Marketing and Sales Practices Litigation.

Counsel, please enter your appearance for the record.

MR. KEGLOVITS: Dave Keglovits, Steve Adams, Amy Fogleman, Adam Doverspike, Wes Pebsworth, of Gable, Gotwals on behalf of plaintiffs.

MR. SILL: Matthew Sill and Katie Griffin on behalf of plaintiffs.

MR. O'CONNOR: Bill O'Connor, Alicia Donahue, and Gabe Egli on behalf of Genentech.

THE COURT: I've reviewed Mr. O'Connor's letter and then I've also reviewed the updated chart that Mr. Keglovits provided. It looks like we're making some progress.

Mr. O'Connor or Ms. Donahue, do you have any other comments or any updates that weren't contained in the letter?

MS. DONAHUE: Good morning, Your Honor. Alicia Donahue.

I think the letter pretty much speaks for itself. I do have, if we get there, some more information about what additional resources and requirements on proportionality issues will be necessary to go dig into that regulatory file that we've identified, and I think we have a proposal for the best

way to handle the additional productions that we intend to make based on what we've found so far in that file. So I'm happy to discuss that. But I'm not sure what the plaintiffs -- you know, I'm not sure what more other than what we've told them in our meet-and-confers we'll be producing, what more, if anything, they're going to be wanting to have. So...

THE COURT: All right. Mr. Keglovits?

MR. KEGLOVITS: Well, I agree, Your Honor, that Genentech has made some progress in understanding its databases now found and some of the people. I'm not going to go farther and say that we have made progress in discovery because we, of course, haven't gotten any of the documents that have been identified in the letter. And there are really, in our view, two substantial areas where we need to I think work on today. I'll be happy to outline those now or wait until the court asks.

THE COURT: Okay. Go ahead.

MR. KEGLOVITS: Well, and if the court read the letter, I'm sure that you saw the focus from Genentech's perspective continues to be on their communications with the FDA. We do not see nor have we heard in the two meet-and-confer calls any kind of data collection efforts with respect to internal documents that we'll be discussing, the issues of relevance. For example, the White e-mail that we attached to our complaint, what has been done to try to capture

that type of information, as well as what has been done to try to capture information that has gone external Genentech but does not involve the FDA. So, that's issue one from our perspective.

Issue two is: What can we do with this regulatory database? We got, I think, a general description of it in a call on Wednesday afternoon and we don't at this point have any idea how it will be made available to us, whether it will be searchable, those kinds of things.

MS. DONAHUE: Your Honor, let me just -- I think if we can kind of put things in perspective on what our understanding of what the plaintiffs are looking for from us. I think they fall really into three categories. It's what did Genentech tell the FDA regarding the mass, volume, or concentration of Herceptin in the vials; what did Genentech know but not disclose to the FDA about that, if anything; and what label submissions were made unilaterally by Genentech, which was the big focus of the hearing last week. So what we have done is scoped -- kind of sectioned things into those categories and figured out what we have or where we might have things related to those.

In regard to what Genentech told the FDA, we've produced to them the CMC section of the initial BLA, we've produced to them the prior approval supplements for Herceptin, we've produced to them documents assoc- -- or will be producing today to them

documents associated with the removal of references to the 21 milliliter yield, which was also a source of a lot of discussion at the hearing, and so that's -- they have that.

In regard to category number two, what did Genentech know but not disclose to the FDA about mass, volume, or concentration, that is contained, for the most part, from based on the search we've done to date in technical reports, that one of which is referenced in the e-mails that they keep referring to. We've told them that we've identified those reports, and this is referenced on page 7 of our letter. We've told them that we've identified those reports, that we're in the process of reviewing them, and that, you know, we will be producing those as they relate to Herceptin after review and redaction, if necessary.

And then onto the third point, what label submissions were made unilaterally by Genentech. We've identified 37 CBEs, which are changes-being-effected submissions, and we are in the process of reviewing those, as well. And so that's where we are, and we've told them that in the meet-and-confer and we've told them that in our letter.

In terms of correspondence, you know, internal correspondence between folks on these issues, anything relevant will be contained in that regulatory file. The regulatory file, as we reference in our letter, is, you know, over four million pages of documents. For us to go through the

regulatory file in order to, you know, know what every single thing that's in there and know what may or may not be responsive on Herceptin and on the issue the plaintiffs keeps focusing on, which is on this internal correspondence issue, is going to take us, you know, well over 2,000 hours at least, I mean, at the very least.

And so what we would propose at this point is that the plaintiffs take stock of what they've got and get our motion on file and look at the declarations that we've submitted that they now have from one company witness and one regulatory expert that is in support of our motion, and from there, if any more is needed to be produced, we continue to discuss it.

But at this point, given the investigation we've done, and we've spent, you know, over 100 hours of attorney time since the last hearing to get to the point we've gotten to now, I honestly -- I said it again, honestly -- but it's just I think we're at the point where the plaintiffs can have sufficient information to review and respond to our motion, and once they've got the motion, if they don't feel that they do, I think we need to have some focused, identified requests that are far more specific than every piece of correspondence or every piece of internal correspondence that might relate to Herceptin since 1997.

THE COURT: So, if there, for example, is an e-mail between two Genentech employees discussing the label or

discussing this drug, what you're telling me is that would be within this regulatory database?

MS. DONAHUE: It could be. I don't have -- it could be. I'm not certain that it is. We also obviously have a number of custodians and custodial files that, again, are thousands and thousands of pages. And, you know, in order to identify what in those files might be related to Herceptin, again, is thousands and thousands of hours.

And internal correspondence about -- I'm having trouble understanding how that is related to the issue at hand, which is preemption. They will, by virtue of what we're producing, they will know what we told the FDA. They already have that. They will know from the studies we're producing what we knew about Herceptin, and if they feel that those studies prove that we knew something, especially the one that's identified in the e-mail, then if they have those studies, they will then know, "Oh, you knew this and you didn't tell the FDA," because that's their allegation apparently. So they've got the studies.

What someone, you know, what someone said about the study at this point is -- may have said in an e-mail -- the value of that compared to what we would have to do to try to search and find and identify correspondence related specifically to Herceptin from custodians or in that file is at this point, I think, you know, unproportional to the issue in the motion.

THE COURT: I don't take -- and Mr. Keglovits, correct

me if I'm wrong -- I don't take the plaintiffs' position to be they want anything that you were aware of and you didn't tell the FDA; in other words, that not telling the FDA is the trigger point for the discovery. My understanding -- and again maybe I've got this wrong -- my understanding is that they just want all correspondence, whether with the FDA or not, related to this drug and its labeling and its content, as well. And it's not -- I mean, there may be information in there that was or was not told the FDA, but I didn't understand, Mr. Keglovits, that that was the threshold question as to whether or not you wanted to see it. Am I wrong about that?

MR. KEGLOVITS: We do, Your Honor, believe that the Supreme Court has set a standard on this precise issue, that Genentech has to show that it was impossible, as they have framed this argument, to change the label, and to do that they have to show clear evidence that the FDA would not have approved a change if they had proposed it. And so where that takes us is: What did Genentech know? And obviously the communications their employees were having with each other about what it knows about, for instance, the concentration on the label, bears directly on it. And --

MS. DONAHUE: Your Honor, the only --

MR. KEGLOVITS: -- let's not forget that this is a national class action that has hundreds of millions of dollars at stake. And so when we're talking about proportionality,

it's, to me, very difficult to understand how looking for those e-mails is not proportional, because any one of them will completely undercut this defense that they have asked the court to consider early.

MS. DONAHUE: Your Honor, --

THE COURT: Go ahead, Ms. Donahue.

MS. DONAHUE: -- the technical studies that are referenced on page 7 of our letter, the ING reports and studies that were submitted that are internal, beyond correspondence, those studies -- that's the basis and repository of any knowledge that Genentech had about the product, about Herceptin, about what may or may not, according to the plaintiffs, should have been on the label regarding concentration, mass, or volume. It's in the studies. They're going to get the studies. Correspondence back and forth about those studies is secondary.

So, at the very least at this point in time, I would suggest that we produce the studies, which we're planning on doing, they take a look at them, and they identify, you know, what past those they want or need over and above the fact that the studies speak for themselves. I mean, if Genentech did a study and a study shows blank, Genentech knew blank. What someone said about it in an e-mail is secondary. And to go through a mass search to find that kind of information in internal correspondence at this point, when they haven't even

looked at the studies we're going to provide them yet, is premature. And, you know, we're talking about 20 years of correspondence.

THE COURT: All right. I want to get back and make sure I understand, though, Mr. Keglovits's approach on this.

I mean, you're not alleging or arguing that you're trying to show that Genentech, I mean, as Ms. Donahue was referring to, committed a fraud on the FDA. You're saying that if there was information that could have been provided the FDA and wasn't, whether or not that was intentional or unintentional or there was any ill intent behind it or whether the intent was entirely pure, that you believe that if you can show that had the FDA obtained that information, then the labeling would have been different, then you can prevail on Genentech's preemption defense.

MR. KEGLOVITS: I think very close to that, although I would say the standard is kind of a negative of what you just said. Genentech has to show that if the FDA had the information that Genentech has, the FDA would have refused to approve a label change.

THE COURT: Yeah. Right. Okay. I think I follow your position there, and I suspect Ms. Donahue may disagree with it. But the point is you just want to know -- I mean, what you're driving at is you want all information available with respect to the labeling of this drug?

MR. KEGLOVITS: Yes, and that includes, for example, in one of the interrogatory responses we just got, it said the FDA initiated a change with respect to concentration because, according to Genentech, the FDA had received complaints from users about the concentration. Well, one would imagine that those complaints might have made their way to Genentech before they made their way to the FDA. Of course, we haven't seen any of those, we don't know whether that's in the regulatory database, and we don't even know if those would have been included in the technical reports, which we also haven't seen.

MS. DONAHUE: Your Honor, a couple of points on the labeling change issue.

First of all, you know, I have to state for the record that we disagree obviously with plaintiffs' interpretation of our impossibility, you know, preemption defense and what our motion will be based on. Our impossibility preemption defense is based on the fact that in order to -- in order to do what plaintiffs apparently think we ought to do, which is have 440 mgs in each vial of Herceptin, we would have to make manufacturing process changes, and that's the basis of the impossibility preemption, and they know that now because they have the declaration from our company witness that's the basis of that position.

So, this concept that we need to show and we plan to and we're going to argue that it would have been impossible for us

to change our label is not the basis of our motion. That's something we need to make clear from the get-go.

In regard to our submissions on labeling changes, if you look at page 5 of our letter, the first full paragraph, I think we lay out there what the label change submission issue is and what we're going to produce in terms of that. This reference to the discovery responses we just served today, yes, that was the 21 mL change that was made at the request of the FDA is we've amended our interrogatory response and we're producing the documents related to that change today.

Over and above that, we've identified I think 36 or 35 additional labeling changes. I don't think very many, if any, relate to the issues in this case, but we are willing to produce them to the plaintiffs and then they will know and have everything that we -- all the labeling changes that we made to Herceptin, whether they were at the request of the FDA or not. So, they will -- and that's what they told you they needed at the hearing, because their position is they need to be able -- they want to be able to show, "Oh, Genentech knew they could make this kind of a change," which, by the way, is dictated by law; what we can and can't change unilaterally is dictated by law, not by Genentech.

So, what I would propose one more time is that they look at what we're going to produce to them before we are forced to go digging into custodial files and, you know, wherever else we

would be finding over 20 years of correspondence on the issue of labeling changes to Herceptin. I just -- it's --

THE COURT: So, Ms. Donahue, what if there is -- I mean, let's talk about this issue of changing the manufacturing process. I mean, if that issue -- and I don't think it's unreasonable to believe it came up at some point within Genentech -- I mean, if that issue is the subject of four or five days or a couple of weeks of e-mails between Genentech engineers or scientists talking about whether or not a label change would require or a change in the manufacturing process or whether or not providing vials with whatever it was, the 21 milliliters of this active ingredient, would require a manufacturing change, I mean, those e-mails between Genentech's employees which may say, "Hey, we would have to change the manufacturing process," or might say, "We wouldn't have to or it wouldn't be that difficult to do it without changing the manufacturing process," I guess I haven't --

MS. DONAHUE: Let me --

THE COURT: -- heard from you that the discovery you're wanting to provide would capture those e-mails.

MS. DONAHUE: Your Honor, the change in the manufacturing process is not something that Genentech has ever considered doing. This drug is approved at a spec of a range that we have told the plaintiffs and Genentech manufactures within that specification.

The impossibility preemption defense is a matter of law and a legal argument. But Genentech internally has not sat around and discussed, "Oh, let's change our manufacturing process." They manufacture a lifesaving drug at a broad spec, and what the plaintiffs are pretty much seeking through this lawsuit is to force Genentech to change the way it makes the drug that saves -- that has been saving lives for 20 years, as approved by the FDA.

So, please do not -- I hope I didn't confuse you by saying -- by pointing out our impossibility preemption defense. It's not something that Genentech has considered doing or plans to do; it's simply a legal defense. I mean, the correspondence there, I can pretty much say for certain there is no correspondence on that because it's not --

THE COURT: But what you're saying is, as part of your defense, is that you would have to change the manufacturing process; right?

MS. DONAHUE: That's the basis of the impossibility preemption defense that plaintiffs keep changing into. It would be impossible for us to change our label.

THE COURT: And you're saying that whether or not you would have to change your manufacturing process is an issue of law?

MS. DONAHUE: I'm saying the impossibility preemption is an issue of law.

THE COURT: Right. But my question is whether or not you would have to change your manufacturing process. You're saying that's an issue of law?

MS. DONAHUE: No; that's as set forth in the declaration of our company witness that they've received. That's an issue of fact.

THE COURT: Right, and so what it seems to me you're saying is, "Trust our company rep; it's going to be too difficult or too time consuming for us to give you any factual materials we might have on what our company rep is saying and so you've just going to have to trust us."

MR. O'CONNOR: Your Honor, Bill O'Connor.

A couple of points here, because I think we're now into, one, plaintiffs misconstruing the impossibility defense, and then about seven layers of assumption since then.

Our first preemption defense is that the federal regulations allow for variation in the actual weight of the drug. And so the heart of their claim, this warranty claim, is that somehow we're supposed to hit 440 on the head, and what the regulations provide is that 440 means what its specification provides, which is 440 XXXXXXXXXXXXXXX. So, that's what we manufacture within. We've produced every lot -- every paper describing every lot of production that establishes the weight is within that range.

So, they love to talk about an improper construction of the

second prong of our preemption defense, and I understand they don't want to talk about number one because they can't overcome it, and it's a stand-alone preemption that ends these claims. So, we're only into impossibility because it's an alternative second stand-alone way for the court to dispose of these claims and it would never have been considered because we comply with the regulations that we've worked on, that the company invested so much in, before its approval in '97 and since.

So, it's really -- I mean, to suggest that there's -- I mean, now to hear speculation from the plaintiffs that there's somehow internal correspondence or memoranda about should we change our manufacturing, no, there would be absolutely none because what we do complies with the specification.

So, we're really -- you know, we're sitting here after -- and again, I don't want to harp on what's been done because I think you're well aware of it, I think you're well aware, too, of the task that we had to go find I guess an e-mail over the course of 20 years, anything that relates to it. But again, that task is certainly not proportional to where we are in this case, which is focusing on the fact that the federal regulation provides a specification that we comply with it, and they're trying to use state law claims to somehow change that regulatory scheme and the framework that is in existence, which is improper.

MR. KEGLOVITS: Your Honor, this is Dave Keglovits.

The answer to your question is yes, they are saying, "Trust us." Back on June 24th when we had this hearing they told Judge Kern what the plaintiffs should do is take stock of what we're going to give them, the CMC, review the motion and review the declarations and then decide what kind of discovery, and Ms. Donahue just repeated that for you, we're now two months down the road from there.

And, you know, ask yourself: Would you have known about this Mr. White e-mail if we didn't get it through an outside source? Would you have known about the complaints that the FDA received if we hadn't had the hearing last week? This stuff is coming out in dribs and drabs. And I know Bill and Alicia are trying as hard as they can to find this information, but I don't have a lot of confidence that their client is really motivated to do what it's supposed to do.

THE COURT: All right. Well, here's what we're going to do. It sounds like some progress has been made in the production of at least documents related to the labeling change and correspondence with the FDA. That should continue to move forward. Genentech should continue to determine where these other documents would be, and not to go sear- -- should not be searching them yet. I'm not directing Genentech to and I don't think anybody wants to, and frankly I think it would be a waste of a lot of time and energy to start reading through these e-mails one at a time. That should not happen and Genentech

should not be doing that.

But in terms of requests that the defendants have made, I think I was clear last time, and I'll say it again this time, what I want Genentech to do is find out what is out there and what would be involved in gathering it together. I don't want to know what would be involved in searching it one at a time. I want to know what would be involved in gathering it together and putting it into some sort of repository that would be searchable, and then I'll make a decision as to whether or not that search ought to take place. But if the search does take place, it will not be a document-by-document search. I think we're about 10 years past doing searches in that manner with ESI. So, I want Genentech to continue that process. It sounds like, Ms. Donahue, you've made quite a bit of progress in that regard and hopefully the rest of this won't take any longer than the time you've spent so far.

What I want to know, and what I think the defendant is entitled to know is: What is out there that is potentially responsive to their discovery requests, where is it, how much data is it, and in what sort of format is it in. And, Ms. Donahue and Mr. O'Connor, you can certainly tell me and tell the plaintiffs how much time it would take to put it into a repository that's searchable. But that's what I want Genentech to continue and work on. In terms of these other documents it is going to produce, Genentech should go ahead and

do that.

Your dispositive motion is due, what, on the 23rd?

MS. DONAHUE: Yes.

THE COURT: All right. Then we'll set another status conference in this case that week of the -- let's see, the 23rd -- I think I'm going to be in that week -- at some point the week of the 23rd. Is that a Monday, the 23rd?

MR. O'CONNOR: It's a Tuesday.

THE COURT: It's a Tuesday? Okay. So probably that Thursday or Friday.

Am I in town, Camie?

THE DEPUTY COURT CLERK: Uh-huh.

THE COURT: Okay. So I'll probably set another telephone conference that Thursday or Friday, and at that point I should be able to know or Mr. O'Connor or Ms. Donahue should be able to tell me, you know, where all this information would be located and how it would be gathered and placed into some sort of a searchable repository. I don't need to know how long it would take you to search it because I'm not going to order anybody to do it. And I will at that point have taken a look at the dispositive motion and we'll certainly have a better feel for what information, additional information, might be relevant and how we might go about conducting the necessary searches to satisfy the plaintiffs' discovery requests on a proportional basis.

In terms of the attorneys'-eyes-only issue, Mr. Keglovits, have you had a chance to talk to Mr. O'Connor and Ms. Donahue about their proposal in their letter?

MR. KEGLOVITS: Well, on Wednesday we had a meet-and-confer. We, the plaintiffs, proposed that, number one, we did not want any attorneys'-eyes-only designation in this case; but, number two, we would agree to limit particular distribution of particular portions of the CMC to eight people initially for purposes of this motion with the caveat that we could come back to you and ask if we wanted to go beyond eight. So that's what we proposed. We heard back from Genentech yesterday that the company was unwilling to do that, and the company again is remaking the argument it's made previously about the need for attorneys' eyes only. As I said, we are unwilling, until we're ordered to, to be burdened by an attorneys'-eyes-only restriction.

THE COURT: So, Mr. Keglovits, you proposed eight -- to have with certain aspects of the discovery that's been produced by Genentech to limit the number of people who could see it to eight?

MR. KEGLOVITS: Yes; what we said is, "If you identify for us what portion of the CMC you want subject to this restriction, we will not go beyond eight employees of our clients, whether they're pharmacists, oncologists, nurses, those kinds of people who could provide us some technical help,

we'll limit it to those eight initially." And obviously, as I said, if we need to go more, we'll come back to you and ask for more, and I think Mr. Sill agreed with that.

THE COURT: And, Mr. Keglovits, on those aspects of it, do you have any problem having those discussions always be with attorneys and not actually providing these eight people with copies of this information?

MR. KEGLOVITS: Yes. Frankly, I am very reluctant to have to handle a large document like this by pulling pages out, especially when the people I'm dealing with know much more about this information than I do. And again, these are not competitors, we're not trying to make Herceptin. We just want to be able to sit down with our own clients and show them what's been produced in the case.

THE COURT: All right. So, Ms. Donahue, I think I've already ruled on this twice. What's the -- why are you making another run at it?

MR. O'CONNOR: Your Honor, Bill O'Connor.

What we have done, and I believe we had told you that we had committed to do, in addition to the discussions on the number of people, we went through the entire production and we basically asked them to agree that there's 500 pages of the production that goes -- that's labeled in the BLA, the CMC section of it, as the drug substance portion. There couldn't be anything that's more trade secret than the formula for

Herceptin. This is the chemistry and the biology. This is not the drug product, which is the issue in this case. They have made allegations about final dosage and we have agreed to remove that or to stop the effort to limit those sections to attorneys' eyes only.

But with respect to the drug substance, which is the active ingredient, which is the fundamental most sensitive information possible, this information is not even disclosed within the company; it's incredibly limited to who has access to that information. It's not supplied to other countries that don't have IP protection. It is -- It could not be treated in a more confidential way.

So, to sit here and listen to the suggestion that the drug substance provisions, that the formulas for the drug is such a burden to them, is a bit frustrating, to say the least, especially -- and again, I know you've heard this, and I know it's been heard several times, and since then there's been a significant effort to identify a discreet number of pages that we are asking for this kind of treatment. It would be wholly inconsistent. And again, I'm not challenging whether Mr. Keglovits or his clients will misuse or do something with it. It's about the protection so that the potential isn't out there. These people change jobs all the time. This industry, the people are moving, they're mobile, and so why would we ever -- why would they ever need the formula for Herceptin? It

has absolutely no relationship to their claims. It has absolutely no relationship to certainly the preemption but ultimately even the merits of the case. If we ever got there, this would still not be at issue. So, I just don't -- Any minor burden on them is far outweighed by the protections that Genentech I think is entitled to on its trade secret formulas.

THE COURT: All right. Mr. Keglovits, anything else on that topic?

MR. KEGLOVITS: No, Your Honor. I think we've heard this several times.

THE COURT: All right. Mr. Keglovits, why don't you pick two of your client representatives, they can view the full scope of the discovery that has either been produced or is going to be produced, including those provisions identified as attorneys' eyes only. If you're able to come back to me and give me a reasonable explanation, of course after having heard response from Genentech as well, as to why the portions that Mr. O'Connor and Ms. Donahue are talking about as to the formula need to be disclosed on a broader basis, in other words, if your client looks at them and says, "Yeah, this would be beneficial to our case to have more people view this," and you can make that argument to me, and Mr. O'Connor and Ms. Donahue don't convince me otherwise, then I might be willing to broaden it. But at this point I'm going to keep it at two. The names of those two people need to be disclosed to

Genentech, and obviously they need to sign the affidavit at the back of the protective order and then we'll go from there.

As to this other information, again, Ms. Donahue, Mr. O'Connor, what I'll expect when we get to this next hearing is for you all to be able to articulate, with respect to the information that the plaintiffs have sought, how you would gather it in a manner that would be searchable, what that would take. And I'm not asking again how long it would take to review this. I'm not asking, you know, arguments about, you know, we might spend a thousand hours looking for one or two e-mails. I'm not concerned with that in the least at this point. What I'm concerned with is: What would it take to gather this information and put it in a repository that actually was searchable. And then by that point I will have had a chance to look at your summary judgment motion and I think make a more informed decision as to how we should proceed with this other discovery. And in the interim, you all should continue to work on the production that has been laid out thus far in your letter.

So, Ms. Donahue, Mr. O'Connor, any questions?

MS. DONAHUE: No, Your Honor. I think we understand. Thank you.

I just want to correct the record on one thing, because I can envision this iss- -- my statement about the issue of fact on the manufacturing changes coming back to haunt me some day,

and especially if you're looking at our motion.

I want to clarify what our impossibility preemption defense is on manufacturing, and it is a legal issue, not a factual issue, and it's that what plaintiffs demand would require manufacturing changes that would require FDA approval. So, just for the record to be clear, I don't want there to be any, you know, misunderstanding that the manufacturing issue is an issue of fact.

Other than that -- and I also want to just respond that Genentech is motivated and is doing everything that the court has requested it to do and ordered it to do and, you know, I don't appreciate Mr. Keglovits saying differently. But that's it. Thank you.

THE COURT: All right. Mr. Keglovits, anything else? Also, obviously if at the next hearing I look at the summary judgment motion and am convinced that we're going to need more discovery, then, Mr. Keglovits, you'll obviously be provided with additional time to respond to that motion for summary judgment.

MR. KEGLOVITS: Thank you, Your Honor.

Can I ask for a little bit of clarification on the order the court just made about the dissemination of this information to two representatives --

THE COURT: Yes.

MR. KEGLOVITS: -- just to make sure I don't do

something I'm not supposed to do?

THE COURT: Sure.

MR. KEGLOVITS: Genentech yesterday pointed us to the table of contents, pages 8, 9, 10 and 11 of the table of contents, and asked that those -- the subject contained within those pages be afforded attorneys'-eyes-only protection. We've gone, and I think it's at least two volumes, I'm not sure how many pages, but could we have them give us the Bates numbers of the pages that would be subject to this two-representative restriction so we can mark it internally to make sure we're not doing what we're not supposed to do?

THE COURT: Mr. O'Connor, any objection to that?

MR. O'CONNOR: I can tell you right now, and we can confirm, but it's BL-8 to BL-509.

MS. DONAHUE: And we'll go back, and if there's additional pages, we'll let you know, but at this point that's what we've identified as that portion. We'll confirm that again.

THE COURT: Okay. All right.

MR. KEGLOVITS: And, Your Honor -- sorry.

THE COURT: No. Go ahead.

MR. KEGLOVITS: To make sure I'm tracking the way the court is thinking, we do now have two declarations, one from a fact witness, one from an expert. Is Your Honor expecting we will not be deposing those people before we come back to the

status conference?

THE COURT: That's right. That's right. I mean, I'll certainly listen to an argument from you that would indicate you want to depose those prior to then, but it seems to me that this will be more efficient if we wait until the next status conference and then we all have a better feel for how much and what the scope of discovery will be and then you can take those depositions at that time if they're still -- if they're warranted.

MR. KEGLOVITS: Thank you, Your Honor. Nothing further from us.

THE COURT: Okay. All right. I appreciate everybody's time. We'll get that hearing set. If you all have any -- just like this last time, if you have any concerns with the setting, then you can talk to Camie and we'll do what we can to accommodate those. Hope everybody has a nice weekend. Thank you.

MS. DONAHUE: Thank you.

MR. O'CONNOR: Thank you.

MR. KEGLOVITS: Thank you, Your Honor. Have a nice weekend.

(PROCEEDINGS CLOSED)

REPORTER'S CERTIFICATION

WHILE NOT PRESENT IN PERSON TO STENOGRAPHICALLY REPORT THE FOREGOING PROCEEDINGS, I CERTIFY THAT IT WAS TRANSCRIBED TO THE BEST OF MY ABILITY FROM A DIGITAL AUDIO RECORDING.

CERTIFIED: *s/Greg Bloxom*

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